

REMARKS

Entry of the foregoing, and further and favorable reconsideration of the subject application pursuant to and consistent with 37 C.F.R. § 1.112 are respectfully requested. By the present Amendment, claim 1 has been amended to more precisely define the claimed invention. Support for the amendment of claim 1 can be found at least on page 22, lines 20 and 21 of the specification as originally filed. Claims 13-21, 22-24, and 27-38 have been deleted without prejudice to or disclaimer of the subject matter contained therein. New claims 43-62 have been added. Support for the added claims may be found in the specification at least on page 21, particularly lines 8 and 25-26. No new matter has been added.

Claim Rejections - 35 U.S.C. § 112

Turning now to the Official Action, Claims 1-12, 22, 25, 26 and 39-42 have been rejected under 35 U.S.C. §112 as indefinite for purportedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In making this rejection, the Examiner argues that Claim 1 is indefinite due to the recitation of "essentially similar to a part of at least 10 consecutive nucleotides" in line 8 and in line 11 of the claim, in that one skilled in the art would purportedly not know what nucleotides are encompassed by this term because it is unclear whether the RNA hairpin comprises a sequence essentially similar to 10 or more consecutive nucleotides of the nucleic acid of

interest, or if it comprises a sequence essentially similar to part of 10 or more consecutive nucleotides of the nucleic acid of interest.

Without conceding to the merits of this rejection, but solely in an effort to expedite prosecution, Applicants have amended claim 1 in a manner that is believed to render this rejection moot. The remaining claims are not dependent upon claim 1, but rather upon claim 2. Nevertheless, Applicants have likewise amended these claims to avoid the use of the rejected term "part". Withdrawal of this rejection is thus respectfully requested.

Claim Rejections - 35 U.S.C. § 102

Claims 1, 2, 3, 7, 8, 11, 12, 22 and 23 have been rejected under 35 U.S.C. 102(b) as being anticipated by Metzloff *et al.*. This rejection, to the extent that it applies to the claims as amended, is respectfully traversed.

In making the rejection, the Examiner has represented Metzloff *et al.* as disclosing a method wherein a foreign transgene, *chsA* has been introduced into petunia plants under control of the 35S promoter from cauliflower mosaic virus whereby the construct produces an RNA molecule comprising a region of 43 bp with 80% homology with *chsA* coding and 3' UTR and capable of forming a hairpin structure, and whereby the expression of this RNA can result in a phenotypic color change. The Examiner maintains that the hairpin disclosed by Metzloff *et al.* is not comprised within the RNA molecule it is normally associated with, and thus qualifies as an artificial hairpin sequence within the meaning of the definition provided by the specification.

To avoid any doubt in the Examiner's mind about what is meant by artificial hairpin, each of the independent claims now explicitly state that the hairpin structure is **artificial** as defined by the proviso that the sense and antisense RNA regions should not naturally occur simultaneously in one RNA molecule. The "sense" and "antisense" regions of the 43 bp stem of the hairpin structure described by Metzloff et al. are indeed naturally occurring in the chsA transcript of the endogenous chsA gene. In other words, the hairpin structure does not comply with any of the provided definitions for an "artificial hairpin structure." Thus, the method disclosed by Metzloff does not meet all the features of the claimed methods and cannot anticipate claims 1, 2, 3, 7, 8, 11, 12, 22 and 23. Withdrawal of the rejection is respectfully requested.


Conclusion

From the foregoing, favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this Amendment, or the Application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 
Malcolm K. McGowan, Ph.D.
Registration No. 39,300

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: April 2, 2002

Attachment to Reply and Amendment dated April 2, 2002

Marked-up Claims 1, 2, 4 and 22

1. (Thrice Amended) A method for reducing the phenotypic expression of a nucleic acid of interest, which is normally capable of being expressed in a eucaryotic cell, comprising the step of introducing a chimeric DNA comprising the following operably linked parts:

- a) a promoter, operative in said eucaryotic cell;
- b) a DNA region, which when transcribed, yields an RNA molecule comprising an RNA region capable of forming an artificial hairpin RNA structure, wherein one of the annealing RNA sequences of the hairpin RNA structure comprises a sense sequence, essentially similar to [a part of] at least 10 consecutive nucleotides of the nucleotide sequence of said nucleic acid of interest, and wherein the second of said annealing RNA sequences comprises [a] an antisense sequence essentially similar to [a part of] at least 10 consecutive nucleotides of the complement of at least part of said nucleotide sequence of said nucleic acid of interest, provided that said sense and said antisense sequence are not naturally occurring simultaneously in one RNA molecule; and optionally
- c) a DNA region involved in transcription termination and polyadenylation.



2. (Amended) A method for reducing the phenotypic expression of a nucleic acid of interest, which is normally capable of being expressed in a eucaryotic cell, comprising the step of introducing a chimeric DNA comprising the following operably linked parts:

- a) a promoter, operative in said eucaryotic cell;
- b) a DNA region, which when transcribed, yields an RNA molecule with a nucleotide sequence comprising
 - i. a sense nucleotide sequence [of] including at least 10 consecutive nucleotides having between about 75 and about 100% sequence identity with at least [part] 10 consecutive nucleotides of the nucleotide sequence of said nucleic acid of interest; and
 - ii. an antisense nucleotide sequence including at least 10 consecutive nucleotides, having about 75% to about 100% sequence identity with the complement of said at least 10 consecutive nucleotides of said sense nucleotide sequence;

wherein the RNA is capable of forming an artificial hairpin RNA structure with a double stranded RNA stem by base-pairing between the regions with sense and antisense nucleotide sequence such that said at least [said] 10 consecutive nucleotides of the sense sequence basepair with said at least 10 consecutive nucleotides of the antisense sequence, provided that said sense sequence and said antisense sequence are not naturally occurring simultaneously in one RNA molecule; and optionally

- c) a DNA region involved in transcription termination and polyadenylation.

Attachment to Reply and Amendment dated April 2, 2002

Marked-up Claims 1, 2, 4 and 22

4. (Amended) The method of claim 2, wherein said sense nucleotide sequence comprises at least about 550 consecutive nucleotides having between 75% and 100% sequence identity with at least [part] about 550 consecutive nucleotides of the nucleotide sequence of said nucleic acid.

22. (Amended) A eucaryotic cell, comprising a nucleic acid of interest, which is normally capable of being phenotypically expressed, further comprising a chimeric DNA molecule comprising the following operably linked parts:

- a) a promoter, operative in said eucaryotic cell;
- b) a DNA region, which when transcribed, yields an RNA molecule with at least one RNA region with a nucleotide sequence comprising
 - i. a sense nucleotide sequence [of] including at least 10 consecutive nucleotides having between 75 and 100% sequence identity with at least [part] 10 consecutive nucleotides of the nucleotide sequence of the nucleic acid of interest; and
 - ii. an antisense nucleotide sequence including at least 10 consecutive nucleotides, having between about 75% to about 100% sequence identity with the complement of said at least 10 consecutive nucleotides of said sense nucleotide sequence;

wherein the RNA is capable of forming an artificial hairpin RNA structure with a double stranded RNA stem by base-pairing between the regions with sense and antisense nucleotide sequence, provided that said sense sequence and said antisense sequence are not naturally occurring simultaneously in one RNA molecule; and optionally

- c) a DNA region involved in transcription termination and polyadenylation.